

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1 – 66 (cancelled)

67. (previously presented) A vaccine for the treatment or prophylaxis of *C. difficile* associated disease, the vaccine comprising a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof which is immunogenic in humans.
68. (previously presented) A vaccine for the treatment or prophylaxis of *C. difficile* associated disease, the vaccine comprising a *C. difficile* gene or *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof to which immunoreactivity is detected in individuals who have recovered from *C. difficile* infection.
69. (previously presented) A vaccine as claimed in claim 67 wherein the gene encodes a *C. difficile* surface layer protein, SlpA or variant or homologue thereof.
70. (previously presented) A vaccine as claimed in claim 67 wherein the peptide/polypeptide is a *C. difficile* surface layer protein, SlpA or variant or homologue thereof.
71. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine comprises a chimeric nucleic acid sequence.

72. (previously presented) A vaccine as claimed in 71 wherein the chimeric nucleic acid sequence is derived from the 5' end of the gene, encoding the mature N-terminal moiety of SlpA from *C. difficile*.
73. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine comprises a chimeric peptide/polypeptide.
74. (previously presented) A vaccine as claimed in 73 wherein the amino acid sequence of the chimeric peptide/polypeptide is derived from the mature N-terminal moiety of SlpA from *C. difficile*.
75. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine contains an amino acid sequence SEQ ID No.1 or a derivative or fragment or mutant or variant thereof.
76. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine contains an amino acid sequence SEQ ID No.2 or a derivative or fragment or mutant or variant thereof.
77. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine contains a nucleotide sequence SEQ ID No.3 or a derivative or fragment or mutant or variant thereof.
78. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine contains a nucleotide sequence SEQ ID No.4 or a derivative or fragment or mutant or variant thereof.
79. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine contains a nucleotide sequence SEQ ID No.5 or a derivative or fragment or mutant or variant thereof.

80. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine contains a nucleotide sequence SEQ ID No.6 or a derivative or fragment or mutant or variant thereof.
81. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine contains a nucleotide sequence SEQ ID No.7 or a derivative or fragment or mutant or variant thereof.
82. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine contains a nucleotide sequence SEQ ID No.8 or a derivative or fragment or mutant or variant thereof.
83. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine contains a nucleotide sequence SEQ ID No.9 or a derivative or fragment or mutant or variant thereof.
84. (previously presented) A vaccine as claimed in claim 67 wherein the vaccine contains a nucleotide sequence SEQ ID No.10 or a derivative or fragment or mutant or variant thereof.
85. (previously presented) A vaccine as claimed in claim 67 in combination with at least one other *C. difficile* sub-unit.
86. (previously presented) A vaccine for the treatment or prophylaxis of *C. difficile* associated disease, the vaccine comprising the mature N-terminal moiety of a surface layer protein, SlpA of *C. difficile* or variant or homologue thereof which is immunogenic in humans.
87. (previously presented) A vaccine as claimed in claim 86 wherein the N-terminal moiety of SlpA contains an amino acid sequence SEQ ID No. 1.

88. (previously presented) A vaccine as claimed in claim 86 wherein the N-terminal moiety of SlpA contains an amino acid sequence SEQ ID No. 2.

89. (currently amended) A vaccine as claimed in claim 67, wherein the vaccine comprises for the treatment or prophylaxis of *C. difficile* associated disease, the vaccine comprising an immunodominant epitope derived from a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative selected from any one of SEQ ID Nos. 3 to 10 or fragment or mutant or variant thereof which is immunogenic in humans.

90. (previously presented) A vaccine as claimed in claim 67 comprising a pharmaceutically acceptable carrier.

91. (previously presented) A vaccine as claimed in claim 67 in combination with a pharmacologically suitable adjuvant.

92. (previously presented) A vaccine as claimed in claim 91 wherein the adjuvant is interleukin 12.

93. (previously presented) A vaccine as claimed in claim 91 wherein the adjuvant is a heat shock protein.

94. (previously presented) A vaccine as claimed in claim 67 comprising at least one other pharmaceutical product.

95. (previously presented) A vaccine as claimed in claim 94 wherein the pharmaceutical product is an antibiotic.

96. (previously presented) A vaccine as claimed in claim 95 wherein the antibiotic is selected from one or more metronidazole, amoxycillin, tetracycline or erythromycin, clarithromycin or tinidazole.

97. (previously presented) A vaccine as claimed in claim 94 wherein the pharmaceutical product comprises an acid-suppressing agent such as omeprazole or bismuth salts.
98. (previously presented) A vaccine as claimed in claim 67 in a form for oral administration.
99. (previously presented) A vaccine as claimed in claim 67 in a form for intranasal administration.
100. (previously presented) A vaccine as claimed in claim 67 in a form for intravenous administration.
101. (previously presented) A vaccine as claimed in claim 67 in a form for intramuscular administration.
102. (previously presented) A vaccine as claimed in claim 67 including a peptide delivery system.
103. (previously presented) An immunodominant epitope derived from a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof.
104. (previously presented) An immunodominant epitope as claimed in claim 103 wherein the *C. difficile* peptide/polypeptide contains an amino acid sequence SEQ ID No.1 or SEQ ID No.2 or a derivative or fragment or mutant or variant thereof.
105. (previously presented) An immunodominant epitope as claimed in claim 101 wherein the *C. difficile* peptide/polypeptide contains an amino acid sequence SEQ ID No.3 or SEQ ID No.4 or SEQ ID No.5 or SEQ ID No.6 or SEQ ID No.7 or SEQ

ID No.8 or SEQ ID No. 9 or SEQ ID No. 10 or a derivative or fragment or mutant or variant thereof.

106. (previously presented) A chimeric nucleic acid sequence derived from the 5' end of the *slpA* gene encoding the mature N-terminal moiety of SlpA from *C. difficile* which is immunogenic in humans.
107. (previously presented) A chimeric peptide/polypeptide wherein the amino acid sequence of the chimeric peptide/polypeptide is derived from the mature N-terminal moiety of SlpA from *C. difficile*.
108. (previously presented) A *C. difficile* peptide comprising SEQ ID No. 1.
109. (previously presented) A *C. difficile* peptide comprising SEQ ID No. 2.
110. (previously presented) A *C. difficile* gene comprising SEQ ID No. 3.
111. (previously presented) A *C. difficile* gene comprising SEQ ID No. 4.
112. (previously presented) A *C. difficile* gene comprising SEQ ID No. 5.
113. (previously presented) A *C. difficile* gene comprising SEQ ID No. 6.
114. (previously presented) A *C. difficile* gene comprising SEQ ID No. 7.
115. (previously presented) A *C. difficile* gene comprising SEQ ID No. 8.
116. (previously presented) A *C. difficile* gene comprising SEQ ID No. 9.
117. (previously presented) A *C. difficile* gene comprising SEQ ID No. 10.

118. (previously presented) The use of a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof which is immunogenic in humans in the preparation of a medicament for use in a method for the treatment or prophylaxis of *C. difficile* infection or *C. difficile* associated disease in a host.
119. (previously presented) The use as claimed in claim 118 wherein the medicament which is prepared is a vaccine.
120. (previously presented) A method for preparing a vaccine for prophylaxis or treatment of *C. difficile* associated disease, the method comprising;
 - obtaining a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof which is immunogenic in humans; and
 - forming a vaccine preparation comprised of said gene or peptide/polypeptide or derivative or fragment or mutant or variant, which is suitable for administration to a host and which when administered raises an immune response.
121. (previously presented) A method as claimed in claim 120 wherein the *C. difficile* peptide/polypeptide contains an amino acid sequence SEQ ID No.1 or SEQ ID No.2 or a derivative or fragment or mutant or variant thereof.
122. (previously presented) A method as claimed in claim 120 wherein the *C. difficile* gene contains an amino acid sequence SEQ ID No.3 or SEQ ID No.4 or SEQ ID No.5 or SEQ ID No.6 or SEQ ID No.7 or SEQ ID No.8 or SEQ ID No.9 or SEQ ID No.10 or a derivative or fragment or mutant or variant thereof.

123. (previously presented) A method for prophylaxis or treatment of *C. difficile* associated disease, the method comprising;

obtaining a *C. difficile* gene or a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof which is immunogenic in humans;

forming a vaccine preparation comprised of said gene or peptide/polypeptide or derivative or fragment or mutant or variant, and

administering the vaccine preparation to a host to raise an immune response.

124. (previously presented) Monoclonal or polyclonal antibodies or fragments thereof, to a *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof which is immunogenic in humans.

125. (previously presented) Monoclonal or polyclonal antibodies or fragments thereof, to *C. difficile* peptide/polypeptide or a derivative or fragment or mutant or variant thereof to which immunoreactivity is detected in individuals who have recovered from *C. difficile* infection.

126. (previously presented) Purified antibodies or serum obtained by immunisation of an animal with a vaccine according to claim 67.

127. (previously presented) The use of the antibodies or fragments as claimed in claim 124 in the preparation of a medicament for treatment or prophylaxis of *C. difficile* infection or *C. difficile* associated disease.

128. (previously presented) The use of the antibodies or serum as claimed in 126 in the preparation of a medicament for treatment or prophylaxis of *C. difficile* infection or *C. difficile* associated disease.

129. (previously presented) The use of the antibodies or fragments or serum as claimed in claim 124 for use in passive immunotherapy for established *C. difficile* infection.
130. (previously presented) The use of the antibodies or fragment or serum as claimed in claim 124 for the eradication of *C. difficile* associated disease.
131. (previously presented) Use of interleukin 12 as an adjuvant in *C. difficile* vaccine.
132. (previously presented) The use of humanised antibodies or serum for passive vaccination of an individual with *C. difficile* infection.